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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,055	10/13/2000	Mark R. Holl		1283

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EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/688,055	HOLL ET AL.	
	Examiner	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 172-177 and 179-212 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 172-177, 179-188, 201, 202, 204, 205 and 209-212 is/are rejected.
- 7) ☒ Claim(s) 189-200, 203 and 206-208 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 172 – 177, 179 – 188, 201, 202, 204, 205 and 209 – 212 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey (U.S. Pat. No. 5,858,195 A). Regarding claims 172, 179 and 180 – 184, Ramsey teaches an apparatus comprising: sample inlet (e.g.,

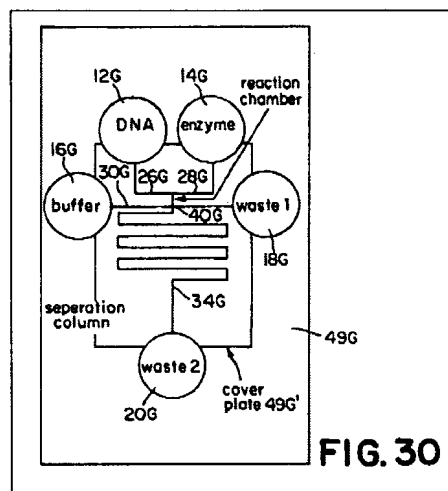
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12G, 14G); a convoluted or serpentine channel structure (34G) in fluidic connection with the sample inlet; and an analysis channel (e.g., the straight portion of channel 34G leading to waste reservoir 20G, which is interrogated using on-chip laser induced fluorescence) in fluidic connection with the convoluted channel structure (see figures 12 & 30) (see col. 15, lines 45 – 63; col. 30, lines 4 – 20).

Ramsey does not specifically teach the incorporation of an interface or opening structure in fluidic connection with the convoluted channel structure and positioned downstream of the sample inlet. Ramsey does not specifically teach an interface or opening structure positioned between the convoluted channel structure and the analysis channel. It is well known in the art to incorporate opening structures within the microchannel networks of microfluidic devices to facilitate cleaning or maintenance procedures. In addition, the use of septums are well known in the art for facilitating effective sealing structures within microfluidic devices (see MPEP § 2144.03). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating such an opening structure within the Ramsey apparatus. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate additional opening structures within the Ramsey apparatus to facilitate the effective cleaning or maintenance of the microfluidic apparatus. Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*,

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15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).



Regarding claims 174 and 175, as shown in figure 30, Ramsey teaches that the serpentine channel (the channel between 34G and 40G) is spatially periodic and also appears isotropic. Regarding claim 176, the width of a channel is $90\ \mu\text{m}$ (see col. 9, lines 1 – 6). Regarding claim 177, the depth of a channel is $5.2\ \mu\text{m}$ (see col. 9, lines 1 – 6). Regarding claims 185 and 186, Ramsey teaches the incorporation of an electrical analysis region, such as a CCD imaging device (see col. 10, lines 36 – 64; col. 11, lines 1 – 21). Ramsey also teaches the use of electrical conductometric measurements in sample detection (see col. 16, lines 48 – 58). Regarding claims 187 and 188, Ramsey teaches the incorporation of optical detection techniques, such as by using laser technology and optical absorbance measurements (see col. 16, lines 48 – 67; col. 17, lines 1 – 67; col. 29, lines 41 – 62). Regarding claim 201, it would have been obvious to incorporate a second analysis region with the first analysis region, since the Courts have held that the mere

duplication of parts without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Regarding claim 202, it would have been obvious to incorporate a second analysis channel, having a second analysis region, in parallel with the first analysis region, since the Courts have held that the mere duplication of parts without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Regarding claim 204, Ramsey teaches the incorporation of a waste storage container (20G) (see figure 30).

Regarding claim 209, the use of alignment markings for positioning such microfluidic devices within a measurement apparatus are well known in the art (see MPEP § 2144.03). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating alignment markings with such an apparatus as that disclosed by Ramsey. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate alignment markings with an microfluidic apparatus for facilitating proper positioning within a measurement apparatus.

Regarding claims 173 and 210 – 212, this claim is a product-by-process claim, where the determination of patentability is based upon the apparatus structure itself. Ramsey indicates that the disclosed microfluidic apparatus may be fabricated using multilayer or photolithographic techniques, which incorporate the use of such materials as plastics and silicon (see col. 8, lines 21 – 59). The patentability of a product or apparatus does not depend on its method of production

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or formation. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP § 2113).

Allowable Subject Matter

Claims 189 – 200, 203 and 206 – 208 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The cited prior art neither teach or fairly suggest the further incorporation a sheath flow assembly in fluidic connection with the first analysis channel upstream of the first analysis region. The cited prior art neither teach or fairly suggest the further incorporation of a reagent inlet in fluid communication with the first analysis channel between the serpentine channel structure and the first analysis region. The cited prior art neither teach or fairly suggest the further incorporation of a sample analysis region comprising a filling status gauge. The cited prior art neither teach or fairly suggest the further incorporation of a waste storage container comprising an expandable compartment. The cited prior art neither teach or fairly suggest the further incorporation of a vent in direct communication with the first analysis channel.

Response to Arguments

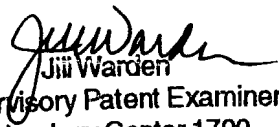
Applicant's arguments with respect to claims 172 – 177 and 179 – 212 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jill Warden
Supervisory Patent Examiner
Technology Center 1700